

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

Translation

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year)

See form PCT/ISA/210

Applicant's or agent's file reference

P1041PC00

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/DE2004/000072

International filing date (day/month/year)

14-01-2004

Priority date (day/month/year)

15-01-2003

International Patent Classification (IPC) or both national classification and IPC

A61K 31/522, A61P 1/08

Applicant

HENNIG ARZNEIMITTEL GMBH & CO. KG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP

Date of completion of this opinion

Authorized officer

Facsimile No.

Telephone No.

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Box No. I

Basis of the report

1. With regard to the language, this opinion has been established on the basis of:
☐ the international application in the language in which it was filed
☐ the translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rule 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ on paper
☐ in electronic form
 - c. time of filing/furnishing
☐ contained in the international application as filed
☐ filed together with the international application in electronic form
☐ furnished subsequently to this Authority for the purposes of search
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. II

Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims, Nos. 1

because:

☒ the said international application, or said claims Nos. 1
relate to the following subject matter which does not require an international search (*specify*):

Claim 1 relates to subject matter which the Examining Authority regards as falling under PCT Article 67.1(iv). Consequently no expert opinion has been established concerning the industrial applicability of the subject matter of this claim.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed (*specify*):

☐ no international search report has been established for said claims Nos. _____

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims		YES
	Claims	1-3	NO
Inventive step (IS)	Claims		YES
	Claims	1-3	NO
Industrial applicability (IA)	Claims	2-3	YES
	Claims	1	NO
2. Citations and explanations:			
<p>1. The PCT Contracting States do not have uniform criteria against which the industrial applicability of claim 1 can be assessed. Patentability may depend on the wording of the claims. For example, the European Patent Office does not recognise the industrial applicability of claims to the medical use of a compound. It may, however, allow claims to the first medical use of a known compound or to the use of such a compound in the preparation of a drug for a new medical application.</p>			
<p>2. This report refers to the following documents:</p>			
<p>D1: "Supportive therapy with dimenhydrinate in combination with cinnarizine in vertigo", THERAPIEWOCHE 1996 GERMANY, Vol. 46, No. 3, 1996, page 175, XP008036745, ISSN 0040-5973</p>			
<p>D2: NOVOTNY et al.: "The Efficacy of Arlevert Therapy for Vertigo and Tinnitus" INTERNATIONAL TINNITUS JOURNAL, Vol. 5, No. 1, 1999, pages 60-62, XP008036719</p>			
<p>D3: "Therapy of vertigo with cinnarizine and dimenhydrinate: Combination treatment is more effective", THERAPIE UND ERFOLG NEUROLOGIE PSYCHIATRIE 1997 GERMANY, Vol. 11, No. 12, 1997, pages 927-928, XP008036746, ISSN 0935-3224</p>			

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

- D4: HALAMA P: "Treatment of vestibular and cerebral vertigo with cinnarizine plus dimenhydrinate" THERAPIEWOCHE 1985 GERMANY, Vol. 35, No. 12, 1985, pages 1422-1426, XP008036742
- D5: NOVOTNY et al.: "Fixed Combination of Cinnarizine and Dimenhydrinate Versus Betahistine Dimesylate in the Treatment of Ménière's Disease", INTERNATIONAL TINNITUS JOURNAL, Vol. 8, No. 2, 2002, pages 115-123, XP008036720

3. PCT Article 33(2)

The application fails to meet the requirements of PCT Article 33(1) because the claims are not novel (PCT Article 33(2)).

Document D1 discloses the treatment of vertigo/dizziness using a fixed combination of dimenhydrinate and cinnarizine ("Arlevert", marketed by the applicant). Document D2 discloses (see the abstract) the treatment of vertigo using "Arlevert". Documents D3 and D4 disclose (see the abstracts) the treatment of dizziness using "Arlevert". Dizziness is treated via both the vestibular and the central points of application. Document D5 discloses the treatment of Ménière's disease, more particularly treatment of the dizziness symptoms associated therewith, using "Arlevert".

The subject matter of the present application thus appears to be comprehensively disclosed by documents D1 to D5.